EXHIBIT 8

Report of Opinions of James L. Gray, III, PharmD, MBA

QUALIFICATIONS

I earned a Bachelor of Science in Pharmacy from the University of Pittsburgh and a Pharm. D. from Duquesne University. I completed my American Society of Health System Pharmacists ("ASHP") accredited residency at Mercy Hospital in Pittsburgh, Pennsylvania.

I am the Executive Director of Pharmacy at Barnes-Jewish Hospital in St. Louis, Missouri and have served in the pharmacy leadership position since 1983. I was a member of the Missouri Board of Pharmacy from 1997 through 2002 and served as its President from 2001 until 2002.

I have been continuously licensed as a pharmacist in the State of Missouri from 1983 until the present.

I am familiar with the recognized standards of acceptable professional practice applicable to the practice of pharmacy in St. Louis, Missouri during the relevant time periods, including throughout 2011 and 2012. Additionally, I am familiar with the recognized standards of acceptable professional practice for the operation of a health system pharmacy in St. Louis, Missouri during the period 2011 and 2012. Such knowledge includes the appropriate standard of care for procuring drugs for use in patients and the oversight and supervision of different operating entities of a health system such as Barnes-Jewish Hospital.

In my opinion, St. Louis and Nashville are similar communities.

More details regarding my education and training, as well as a list of my publications is contained in my *curriculum vitae*, copy attached. I have not testified as an expert witness during the past four years.

INFORMATION REVIEWED

My statements are based on my background, training and experience as well as the following information, which I reviewed:

- Documents regarding the regulatory history of New England Compounding Pharmacy, Inc., d/b/a/ New England Compounding Center ("NECC");
- Information from the United States Centers for Disease Control and Prevention ("CDC"), including the *Morbidity and Mortality Weekly Report* dated December 13, 2002 regarding certain cases of fungal meningitis caused by contaminated epidural steroids made by a compounding pharmacy;
- Information from a October 23, 2003 hearing before the United States Senate's Committee on Health, Education, Labor, and Pensions regarding pharmacy compounding;

- Information published by the United States Food and Drug Administration ("FDA") regarding compounded drug products, compounding pharmacies, and the risks associated with compounded drugs;

- Information published by The American Society of Health System Pharmacists warning the pharmacy and medical community of the risks of using compounded drugs;

- Certain federal, Tennessee and Massachusetts pharmacy laws governing pharmacy compounding; and

- The depositions of Debra Schamberg, R.N., John Culclasure, M.D., Jeff Ebel, Carmen Leffler, D.Ph., Martin Kelvas, D.Ph., and Terry Grinder, D.Ph., all with exhibits, as well as portions of the deposition of Michael Schatzlein, M.D.

- United States Pharmacopeia (USP) (2008) Chapters 795 & 797 which establish national standards for non-sterile and sterile drug compounding respectively.

SUMMARY OF FACTS

The substance of the facts and opinions are developed through my review of pertinent documents and deposition testimony taken in this case. In addition, I am relying on my education, training and experience including where applicable pertinent and relevant literature.

Dangers associated with Compounded Drugs

Traditional pharmacy compounding is defined as a process where a pharmacist combines, mixes, or alters ingredients to produce a medication that is custom made to meet a specific medical need based on an individual physician prescription for a specific patient. However, over the 30 years leading up to the NECC disaster (2012) some compounding pharmacies morphed into "non-traditional" pharmacy compounders. Specifically, these pharmacies engaged in production and shipment of large volumes of compounded drugs across state lines, compounded drugs that are essentially copies of FDA-approved commercially available drugs, compounded drugs outside of a pharmacist-patient-physician relationship without an individual patient prescription, and, finally, provided compounded drugs to third parties for sale, such as hospitals, clinics, physician offices, and home health providers. In effect, these compounding pharmacies operated like manufacturers while hiding under the mantel of state board of pharmacy regulation. In this way they avoided extensive federal regulations (cGMP -21 CFR Parts 210 and 211 enforced by the FDA) designed to insure a supply of safe and effective medications. For example, NECC was one such non-traditional compounding pharmacy operating under state board of pharmacy licensure while compounding slightly modified copies of FDA approved and regulated commercial products (such as methylprednisolone acetate- MPA) from non-sterile bulk chemicals (USP 797 high risk compounding). NECC then shipped large bulk quantities of these high risk products across state lines without required individual patient prescriptions, for use in epidural steroid injections. NECC offered lower prices than the commercially manufactured FDA approved products while they touted that their version of the steroids were preservative free, unlike the FDA approved version of the drugs. However, these compounded drugs were not